

REMARKS

Applicants note with appreciation the Examiner's withdrawal of the rejection of Claim 95 under 35 U.S.C. §102(b) as being anticipated by Hashi et al. Applicants have canceled Claim 90-94, and 96-97, and reserve the right to file one or more divisional applications drawn to the subject matter contained within those claims.

Applicants have amended Claim 95 to point out that the purified polypeptide facilitates the binding of a retroviral vector to a target cell, wherein a gene is carried into the target cell by the retroviral vector. Further, the Applicants have removed the phrase "functional equivalents" and indicated that the polypeptide comprises SEQ ID No. 5 or a polypeptide encoded by a gene which hybridizes to the complement of SEQ ID No. 26 under highly stringent conditions.

Applicants respectfully submit that support can be found on page 19, lines 18 to 25, and page 28, lines 1 to 29, which illustrate the Applicants' highly stringent hybridization procedures, and the relationship between the polypeptide of SEQ ID No. 5 and the gene which encodes for it, SEQ ID No. 26. Applicants respectfully submit that Claim 95 is analogous to Example 9 of the Revised Interim Written Description Guidelines promulgated by the USPTO (copy enclosed). Example 9 illustrates a claim to a gene, which hybridizes to the complement of a sequence to encode a protein with a particular function. Similarly, the Applicants claim a gene which must hybridize to the complement of SEQ ID No. 26 under highly stringent condition and encode a protein, which facilitates the binding of a retroviral vector to a target cell. As a result, the Applicants have defined particular genes which hybridize to SEQ ID No. 26 and encode a protein with specific activity.

In drawing analogy to the claims set forth in Example 9 of the Interim Description Guidelines, the Applicants respectfully submit that the phrase "a polypeptide encoded by a gene which hybridizes to the complement of SEQ ID No. 26 under highly stringent condition," is directly

analogous to Claim 1 of Example 9, which states “an isolated nucleic acid that hybridizes under highly stringent condition to a sequence set forth in SEQ ID No. 1 wherein the nucleic acid encodes a protein binding to the dopamine receptor.” Applicants recite that a gene (e.g. nucleic acid) must specifically hybridize under highly stringent conditions to the complement of SEQ ID No. 26. Further, the Applicants’ gene (e.g. nucleic acid) must encode a protein with a defined and specific activity.

Applicants have used alternative language, which has long been recognized by the Patent Office and Federal Courts. Claim 95 recites “a polypeptide consisting of SEQ ID No. 5 or a polypeptide encoded by a gene which hybridizes to the complement of SEQ ID No. 26 under highly stringent conditions.” In other words, amended Claim 95 simply means that the polypeptide will be either that of SEQ ID No. 5 or a polypeptide encoded for a gene hybridizing to SEQ ID No. 26. In particular, M.P.E.P., § 2173.05(h), has clearly authorized the use of “or” terminology when it states that:

Alternative expression using “or” are acceptable, such as “wherein r is a, b c or d.” The following phrases were held to be acceptable and not in violation of 35 U.S.C. §112, second paragraph, in *In re Gaubert*, 524 F.2d 122, 187 U.S.P.Q. 664 (C.C.P.A 1975): “made entirely or in part of at least one piece”; “Iron, Steel, or any other magnetic material.”

In view of the foregoing, Applicants respectfully submit that the use of alternative language in Claim 95 is clearly recognized by the Patent Office.

One skilled in the art would recognize that hybridization techniques using a known DNA probe (e.g. SEQ ID No. 26) under stringent conditions was conventional at the time of filing. In fact, Applicants have provided exemplary hybridization procedures, which one skilled in the art could readily follow to find and ascertain the activity of any gene, that hybridized to SEQ ID No. 26.

(Applicants' Specification, page 28, line 16, to page 29, line 6). Furthermore, the Applicants have provided a number of examples illustrating the isolation of cell adhesion proteins, including that of SEQ ID No. 5. Applicants respectfully request withdrawal of the rejection of Claim 95 under 35 U.S.C. §112, first and second paragraphs.

In view of the foregoing, Applicants respectfully submit the Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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e.g. expression vectors, the necessary common attribute is the ORF (SEQ ID NO: 2).

Weighing all factors including (1) that the full length ORF (SEQ ID NO: 2) is disclosed and (2) that any substantial variability within the genus arises due to addition of elements that are not part of the inventor's particular contribution, taken in view of the level of knowledge and skill in the art, one skilled in the art would recognize from the disclosure that the applicant was in possession of the genus of DNAs that comprise SEQ ID NO: 2.

Conclusion: The written description requirement is satisfied.

Example 9: Hybridization

Specification: The specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. The specification includes an example wherein the complement of SEQ ID NO: 1 was used under highly stringent hybridization conditions (6XSSC and 65 degrees Celsius) for the isolation of nucleic acids that encode proteins that bind to dopamine receptor and stimulate adenylate cyclase activity. The hybridizing nucleic acids were not sequenced. They were expressed and several were shown to encode proteins that bind to a dopamine receptor and stimulate adenylate cyclase activity. These sequences may or may not be the same as SEQ ID NO: 1.

Claim:

An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1,

wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

Analysis:

A review of the full content of the specification indicates that the essential feature of the claimed invention is the isolated nucleic acid that hybridizes to SEQ ID NO: 1 under highly stringent conditions and encodes a protein with a specific function. The art indicates that hybridization techniques using a known DNA as a probe under highly stringent conditions were conventional in the art at the time of filing.

The claim is drawn to a genus of nucleic acids all of which must hybridize with SEQ ID NO: 1 and must encode a protein with a specific activity.

The search of the prior art indicates that SEQ ID NO: 1 is novel and unobvious.

There is a single species disclosed (a molecule consisting of SEQ ID NO: 1) that is within the scope of the claimed genus.

There is actual reduction to practice of the disclosed species.

Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of

skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Conclusion: The claimed invention is adequately described.